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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/897,728 | 07/03/2001 | John F. Wironen | RTI-133 | 8170 |

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| EXAMINER |
|---|
| SMITH, CAROLYN L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/897,728 | WIRONEN ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn L Smith | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Restriction/Election*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn to a method for quantifying the osteoinductive potential of a collection of like implant material intended for implantation, classified in class 702, subclass 30. If this Group is elected, then the below summarized specie election is also required.

II. Claim 24, drawn to a method of measuring the chondrogenic capacity of an implant, classified in class 702, subclass 19.

III. Claims 25-26, drawn to a method of accelerating wound healing or rate of recovery from bone damage or disease, classified in class 435, subclass 7.1 and class 604, subclass 543. If this Group is elected, then the below summarized specie election is also required.

IV. Claims 27 and 29-30, drawn to a method for the diagnosis and treatment of bone or soft-tissue cancer, classified in class 436, subclass 64. If this Group is elected, then the below summarized specie election is also required.

V. Claim 28, drawn to a method for assessing developmental bone or tissue disorders, classified in class 600, subclass 562. If this Group is elected, then the below summarized specie election is also required.

VI. Claim 31, drawn to a method for reducing the need to sacrifice laboratory animals used in bone growth studies, classified in class 604, subclass 175. If this Group is elected, then the below summarized specie election is also required.

VII. Claims 32-33, drawn to an implant or collection of implants, classified in class 424, subclass 549. If this Group is elected, then the below summarized specie election is also required.

VIII. Claims 34-36, drawn to a composition for administration, classified in class 514, subclass 1.

**Specie Election Requirements for Groups I and III-VII:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Group I: This Group contains patentably distinct species, particularly bone implant materials. If this Group is elected, please select one of the bone implant material types or a specific combination of two types listed in claim 3, so that initial examination of the application may proceed.

For Groups I and III-VII:

These Groups contain patentably distinct species, particularly osteoinductive/osteogenic factors. If one of these Groups is elected, please select one of the osteoinductive/osteogenic factors or a combination of two factors listed in claims 13-15, so that initial examination of the application may proceed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness or independence of various bone implant materials (Group

I) is because each is directed to an implant material from distinctly different locations or situations. The distinctness or independence of various osteoinductive/osteogenic factors (Groups I and III-VII) because each is directed a composition with distinctly different structures and features.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I-II and IV-VII] and [III and VIII] are independent inventions because they are directed to different chemical types regarding the critical limitations

therein. For Groups I-II and IV-VII, the critical feature is an implant. For Groups III and VIII, the critical feature is a composition. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Thus, the two Groupings [I-II and IV-VII] and [III and VIII] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I-II and IV-VII are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the implant of Group VII may be utilized in distinct usages as needed in Group I for a method of quantifying the osteoinductive potential of a collection of like implant material intended for implantation, in a method of measuring the chondrogenic capacity of an implant as in Group II, in a method for diagnosis and treatment of bone or soft-tissue cancer as in Group IV, in a method for assessing developmental bone or tissue disorders as in Group V, in a method for reducing the need to sacrifice laboratory animals as in Group VI, or alternatively, in a method for developing a pharmaceutical composition. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups III and VIII are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Group VIII may be utilized in distinct usages as needed in Group III in a method of accelerating wound healing or rate of recovery from bone damage or disease as in Group III, or alternatively, in a method of treating cancer. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 22, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER